

REMARKS

Applicants express appreciation to the Examiner for consideration of the earlier amendment and remarks and withdrawal of the finality of the previous Office Action.

Claims 19, 22, 23, 30-38, 40, 43-48, 50, 53-54, 61-69, 71, and 74-79 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,551,419 to Froehlich et al. ("Froehlich") in view of U.S. Patent No. 5,704,345 to Berthon Jones ("Berthon-Jones") and U.S. Publication No. 2002/0088465 to Hill ("Hill"). In response, claims 19, 34, 36, 50, 65, and 67 are being amended and claims 35 and 66 are being cancelled. In particular, the independent claims are being amended to make clear that the limitation associated with "indices" is not in the claims and that the controller's determination of sleep disordered breathing is related to identifying such events and not based directly on calculating indices.

In the present Office Action, the Examiner relies on Froehlich for a variety of disclosures, including "known techniques" and on Berthon-Jones for the use of indices. However, the functionality of the processor of the present invention is not disclosed or suggested by Froehlich or Berthon-Jones (or Hill) and the use of indices is no longer a part of the claims.

The independent claims (claims 19, 34, 50, and 65) are directed to methods and apparatus which include a controlled blower. The control of the blower is key to

the claims and is distinct from any disclosure or suggestion in the cited references.

In the present claims, the controller performs several functions:

- The controller processes two different signals – a pressure signal and a flow signal,
- From the two signals, the controller determines the presence of two distinct sleep disordered breathing events,
- From the patient's breathing cycle, the controller determines the transitions between inspiration and expiration,
- The controller controls a first pressure, delivered in synchrony with a first transition, and determined based upon the first event, and
- The controller controls a second pressure, delivered in synchrony with a second transition, and determined based upon the second event.

Notably, each of the events is determined independently from the other and each is based on a different manifestation of sleep disordered breathing. These two determined events are used to set two different pressure treatment levels for treating a patient, each set independently of the other. In some claims, the two manifestations are 1) apnea, hypopnea, or snoring, and 2) flow flattening. The cited references either set one treatment level or set two treatment levels based upon a single-sourced event, and none of the references is directed to independently setting two parameters based on two different manifestations of sleep disordered breathing.

As stated in the Remarks to the Amendment submitted on May 14, 2010, Froehlich does not independently set two different parameters.

While the Froehlich reference does teach bi-level operation and adjustments based on the detection of respiratory events, the two pressure waveforms (for the two phases of a respiratory cycle) are not changed independently based on the detection of respective types of respiratory events. ... And the secondary reference, Berthon-Jones, also does not teach this feature of separate pressure controls for the two phases based on detection of respective types of respiratory events.

In the present Office Action (page 3), the Examiner points out that Berthon-Jones calculates an index for apnea and an index for flow flattening using the same measure. The Berthon-Jones approach is completely different from the approach of the present claims in that the present claims use different signals (pressure and flow) where Berthon-Jones uses a single signal. The use of one signal to identify one event and to set one pressure level and a second signal to identify a second event and to set a second pressure level is not disclosed or suggested by either Berthon-Jones or Froehlich. The Examiner acknowledges this at the beginning of the full paragraph on page 4 of the present Office Action.

Hill is relied upon specifically for using indices to vary both IPAP and EPAP to counter a single sleep disordered breathing event. (Office Action, page 3, last paragraph). However, as amended, there are no indices in the present claims. In addition, as detailed in the remarks to the previous amendment, Hill is directed “to determin[ing] whether the patient is experiencing Cheyne-Stokes breathing” and does so by monitoring peak flow (paragraph 0011). Hill does not monitor pressure

or any other measure of flow in determining whether the patient is suffering from Cheyne-Stokes breathing. The two indices in Hill identified by the Examiner are referred to in these remarks as “Hill’s IPAP index” and “Hill’s EPAP index” and each is set based on an indication of Cheyne-Stokes respiration (CSR), which is identified based on peak flow. Hill’s IPAP index (discussed in detail in Hill’s paragraphs 0049-0051) is based only on measured peak flow and a target peak flow (see paragraph 0049) and is used to set IPAP. Hill’s EPAP index (discussed in detail in Hill’s paragraphs 0060-0066) is comprised of three identified components (see FIG. 3) – (1) a CSR shape index, which is based on a sequence of peak flows, (2) a CSR severity index, which is calculated from an array of peak flows, and (3) a pressure support index, which is “a measure of amount of assistance that is being provided by the pressure support system in attempt to combat the CSR cycle” (paragraph 0065). The pressure support index is not a measure of a parameter associated with the CSR cycle. (paragraph 0065). With regard to sensed data, both indices in Hill are based on the same sensed data – peak flow. In Hill, the same determined characteristic is used to indication change both IPAP and EPAP, even though IPAP and EPAP may be changed differently and at differently times. It is clear from reading Hill that there is only one type of sleep disordered breathing that prompts all changes – CSR – and that only one sensed characteristic – peak flow – is used for all adjustment. Hill does not disclose or suggest the present claims, in which two characteristics are determined independently of each other, each of which is used for establishing a different pressure treatment. In the absence of two different types

of characteristics (or events) that cause adjustments of different ones of IPAP and EPAP, Hill cannot possibly anticipate the claims in issue.

For the reasons described above, none of Berthon-Jones, Froehlich, or Hill, either alone or in combination, disclose or suggest claims 19, 34, 50, 65, or the claims which depend upon them. The early passage to issue of the application is respectfully requested.

If any additional fee is required, the Commissioner is hereby authorized to charge the amount of any such fee to Deposit Account No. 07-1730, Docket No. 3869-038.

Respectfully submitted,
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Dated: February 14, 2011